



Translation

## PATENT COOPERATION TREATY

## PCT

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY  
(Chapter II of the Patent Cooperation Treaty)

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference  S-562WO-0428	FOR FURTHER ACTION		See Form PCT/IPEA/416
International application No.  PCT/JP2004/006216	International filing date ( <i>day/month/year</i> )  28 April 2004 (28.04.2004)	Priority date ( <i>day/month/year</i> )  30 April 2003 (30.04.2003)	
International Patent Classification (IPC) or national classification and IPC C07D 513/04, B01D 9/02 // A61K 31/496, A61P 31/04			
Applicant  NIPPON SHINYAKU CO. LTD.			

<p>1. This report is the international preliminary examination report, established by this International Preliminary Examining Authority under Article 35 and transmitted to the applicant according to Article 36.</p> <p>2. This REPORT consists of a total of <u>3</u> sheets, including this cover sheet.</p> <p>3. This report is also accompanied by ANNEXES, comprising:</p> <p>a. <input type="checkbox"/> (<i>sent to the applicant and to the International Bureau</i>) a total of _____ sheets, as follows:</p> <p><input type="checkbox"/> sheets of the description, claims and/or drawings which have been amended and are the basis of this report and/or sheets containing rectifications authorized by this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions).</p> <p><input type="checkbox"/> sheets which supersede earlier sheets, but which this Authority considers contain an amendment that goes beyond the disclosure in the international application as filed, as indicated in item 4 of Box No. I and the Supplemental Box.</p> <p>b. <input type="checkbox"/> (<i>sent to the International Bureau only</i>) a total of (indicate type and number of electronic carrier(s)) _____, containing a sequence listing and/or tables related thereto, in computer readable form only, as indicated in the Supplemental Box Relating to Sequence Listing (see Section 802 of the Administrative Instructions).</p> <p>4. This report contains indications relating to the following items:</p> <ul style="list-style-type: none"> <li><input checked="" type="checkbox"/> Box No. I Basis of the report</li> <li><input type="checkbox"/> Box No. II Priority</li> <li><input type="checkbox"/> Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability</li> <li><input type="checkbox"/> Box No. IV Lack of unity of invention</li> <li><input checked="" type="checkbox"/> Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement</li> <li><input type="checkbox"/> Box No. VI Certain documents cited</li> <li><input type="checkbox"/> Box No. VII Certain defects in the international application</li> <li><input type="checkbox"/> Box No. VIII Certain observations on the international application</li> </ul>
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Date of submission of the demand  30 November 2004 (30.11.2004)	Date of completion of this report  03 March 2005 (03.03.2005)
Name and mailing address of the IPEA/JP	Authorized officer
Facsimile No.	Telephone No.

## INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.

PCT/JP2004/006216

## Box No. I Basis of the report

1. With regard to the language, this report is based on the international application in the language in which it was filed, unless otherwise indicated under this item.

- This report is based on translations from the original language into the following language \_\_\_\_\_, which is language of a translation furnished for the purpose of:
- international search (under Rules 12.3 and 23.1(b))
  - publication of the international application (under Rule 12.4)
  - international preliminary examination (under Rules 55.2 and/or 55.3)

2. With regard to the elements of the international application, this report is based on (replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report):

- The international application as originally filed/furnished  
 the description:  
 pages \_\_\_\_\_, as originally filed/furnished  
 pages\* \_\_\_\_\_ received by this Authority on \_\_\_\_\_  
 pages\* \_\_\_\_\_ received by this Authority on \_\_\_\_\_
- the claims:  
 pages \_\_\_\_\_, as originally filed/furnished  
 pages\* \_\_\_\_\_, as amended (togeter with any statement) under Article 19  
 pages\* \_\_\_\_\_ received by this Authority on \_\_\_\_\_  
 pages\* \_\_\_\_\_ received by this Authority on \_\_\_\_\_
- the drawings:  
 pages \_\_\_\_\_, as originally filed/furnished  
 pages\* \_\_\_\_\_ received by this Authority on \_\_\_\_\_  
 pages\* \_\_\_\_\_ received by this Authority on \_\_\_\_\_
- a sequence listing and/or any related table(s) – see Supplemental Box Relating to Sequence Listing.

3.  The amendments have resulted in the cancellation of:

- the description, pages \_\_\_\_\_
- the claims, Nos. \_\_\_\_\_
- the drawings, sheets/figs \_\_\_\_\_
- the sequence listing (specify): \_\_\_\_\_
- any table(s) related to sequence listing (specify): \_\_\_\_\_

4.  This report has been established as if (some of) the amendments annexed to this report and listed below had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).

- the description, pages \_\_\_\_\_
- the claims, Nos. \_\_\_\_\_
- the drawings, sheets/figs \_\_\_\_\_
- the sequence listing (specify): \_\_\_\_\_
- any table(s) related to sequence listing (specify): \_\_\_\_\_

\* If item 4 applies, some or all of those sheets may be marked "superseded."

## INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.

PCT/JP2004/006216

**Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**

**1. Statement**

Novelty (N)	Claims	1-5	YES
	Claims	6	NO
Inventive step (IS)	Claims	1-5	YES
	Claims	6	NO
Industrial applicability (IA)	Claims	1-6	YES
	Claims		NO

**2. Citations and explanations (Rule 70.7)****List of documents****Document 1:**

KAKEMI, Kazuo et al., Chemical structure, physicochemical properties, and stability of prulifloxacin, Iyakuhin Kenkyu, January 20, 1997, Vol. 28, No. 1, p. 1-11

**Document 2:**

JP 1-294680 A (Nippon Shinyaku Co., Ltd.) November 28, 1989 & EP 315828 A1 & EP 315828 B1 & JP 07051579 B4 & AT 74608 E & ES 2031569 T3 & ZA 8808186 A & AU 8824673 A1 & AU 608911 B2 & DK 8806163 A & DK 172077 B1 & CN 1033055 A & CN 1024194 B & FI 8805128 A & FI 88618 B & FI 88618 C & NO 8804958 A & NO 177934 B & NO 177934 C & CA 1316925 A1 & IL 88303 A1 & US 5086049 A

**Claim 6**

Based on the description in document 1 cited in the international search report, the invention of claim 6 lacks novelty and an inventive step.

Document 1 states that three crystalline forms (type I, type II, and type III) are obtained depending on crystallization conditions when recrystallization of prulifloxacin from acetonitrile is performed (see page 4, "section 2.1 Crystal Forms").

In light of the fact that acetonitrile is used as the recrystallization solvent, this examination finds that an acetonitrile solvate of prulifloxacin will be formed among the crystals obtained by recrystallization described in document 1.

Generally speaking, after recrystallization, the final crystals are obtained after going through a drying process by conventional means such as heating the crystals obtained thereby under reduced pressure. Therefore, this examination finds that in the method for producing type III crystals of prulifloxacin recrystallized from acetonitrile described in document 1 includes a process step wherein the solvent of the acetonitrile solvate of prulifloxacin produced by recrystallization from acetonitrile is removed by a conventional drying process to produce type III crystals of prulifloxacin.

**Claims 1-5**

The inventions of claims 1-5 are novel and involve an inventive step with respect to documents 1 and 2 cited in the international search report.

Documents 1 and 2 neither describe nor suggest the inventions of claims 1-5.